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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,533	09/01/2006	Yoshinobu Yamazaki	Q96716	6983

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EXAMINER	
BLAKELY III, NELSON CLARENCE	
ART UNIT	**PAPER NUMBER**
1629	

NOTIFICATION DATE	DELIVERY MODE
10/12/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO@sughrue.com
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Office Action Summary	Application No.	Applicant(s)	
	10/598,533	YAMAZAKI ET AL.	
	Examiner	Art Unit	
	NELSON BLAKELY III	1629	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-13* is/are pending in the application.

5a) Of the above claim(s) *4, 5 and 7-12* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-3,6 and 13* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/08/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application Status

Claims 1-13 of the instant application are pending. Claims 4, 5 and 7-12 are withdrawn pursuant to Applicant's response, filed 09/01/2011. Accordingly, instant claims 1-3, 6 and 13 are presented for examination on their merits.

Applicant's Arguments, filed 09/01/2011, have been fully considered. Rejections/objections not reiterated from previous Office Actions are hereby ***withdrawn***. The following rejections/objections are either reiterated or newly applied. They constitute the complete set of rejections/objections presently being applied to the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed on 09/01/2011, has been entered.

Election/Restrictions

As recited in a previous Office action, Applicant's elections ***without traverse*** are:

a) a disclosed indoline derivative represented by formula (I) as (-)-1-(3-hydroxypropyl)-5-((2R)-2-{[2-[(2,2,2-trifluoro-ethyl)oxy]phenyl}oxy)ethyl]amino}propyl)-2,3-dihydro-1H-indol-7-carboxamide (also known as KMD-3213 or silodosin);

b) at least one disclosed neurogenic disorder as spinal cord involvement; and

c) wherein the method does NOT further comprise administration in combination with one or more other agents.

Information Disclosure Statement

The Information Disclosure Statement, filed 04/08/2011, is acknowledged and considered.

Applicant's Amendment

Applicant's amendment, filed 09/01/2011, wherein claims 4, 5 and 7-12 are withdrawn, and claim 13 is added, is acknowledged.

Response to Arguments

Applicant's arguments, with respect to claims 1-3 and 6, have been considered, but are moot in view of the new grounds of rejection.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muramatsu *et al.* (International Publication No. WO99/15202; cited by Applicant), in view of Ishizuka (Geriatric Medicine, Vol. 41, No. 8, pages 1149-1153; 2003; provided in a previous Office action), as evidenced by Ohashi *et al.* (Caretaker Group Federation Monthly, Vol. 8, No. 591, pages 57-60; 1998; provided in a previous Office action) and

Garvey *et al.* (U.S. Patent Application Publication No. 2002/0143007A1; cited by Applicant).

With regard to instant claims 1-3, 6 and 13, Muramatsu *et al.* disclose, in the abstract, remedies for dysuria resulting from prostatic hypertrophy, which contain a highly selective α_1-adrenergic receptor blocker, e.g., silodosin.

Muramatsu *et al.* fail to disclose specifically wherein the remedies, or methods, are for the treatment of overactive bladder accompanied with neurogenic disorders, e.g., spinal cord involvement. However, Ishizuka discloses, on page 11 of the document, wherein α_1 receptors are extremely important in the manifestation of overactive conditions. Further, Ishizuka discloses, in the instant excerpt, an overview of the relation between overactive bladder, which is a new concept having urination urge as its chief symptom and hypertrophy of the prostate gland. Ishizuka discloses wherein α_1 blockers are the main therapeutic agent for hypertrophy of the prostate gland. On page 4, Ishizuka discloses wherein spinal cord injuries and other nerve impairments are factors which cause overactive bladder. For evidentiary purposes, Ohashi *et al.* disclose, on page 2 of the document, wherein hyperactive bladder and unstable bladder are illnesses which cause urge incontinence. In the instant excerpt, Ohashi *et al.* further disclose wherein hyperactive bladder is a sequelae to cerebral hemorrhage, Parkinson's disease and spinal damage. Additionally, Garvey *et al.* disclose, in reference claims 37, 38 and 51, pages 47 and 48, a method for treating benign prostatic hyperplasia, a neurodegenerative disorder, urge incontinence or overactive bladder in a patient in

need thereof comprising administering to the patient a composition comprising KMD 3213 (silodosin).

With regard to instant claim 13, the transitional phrase "consisting essentially of" is noted. It is understood that the aforementioned phrase limits the scope of the claim to the specified materials or steps, and those that do not materially affect the basic and novel characteristics, of the claimed invention. For purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising". Furthermore, Garvey *et al*. was provided for evidentiary purposes to illustrate the nexus between the highly selective α_1-adrenergic receptor blocker, e.g., silodosin, useful in the methods for treating benign prostatic hyperplasia (See Muramatsu *et al*. and Ishizuka) and urge incontinence, overactive bladder and spinal cord injuries (See Ishizuka and Ohashi *et al*.).

Therefore, a skilled artisan would have envisaged the instantly claimed method for the treatment of overactive bladder accompanied with spinal cord involvement, as disclosed by Muramatsu *et al*., in view of Ishizuka, as evidenced by Ohashi *et al*. Garvey *et al*. One of ordinary skill in the art would have been motivated to combine the teachings of the aforementioned references when seeking a method that effectively treats overactive bladder wherein a pharmacotherapy is preferred without the need of a risky and an invasive surgery. It would have been obvious to one of ordinary skill in the

art, at the time of the invention, because the combined teachings of the prior art are suggestive of the claimed invention.

Accordingly, the instant invention, as claimed in claims 1-3, 6 and 13, is *prima facie* obvious over the combination of the aforementioned teachings.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to NELSON BLAKELY III whose telephone number is (571)270-3290. The Examiner can normally be reached on Mon - Thurs, 7:00 am - 5:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey S. Lundgren can be reached on (571) 272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. B. III/
Examiner, Art Unit 1629

/Jeffrey S. Lundgren/
Supervisory Patent Examiner, Art Unit 1629